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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,049	07/24/2001	Thomas G. Rehberger	362.003	4550

23598 7590 08/18/2003

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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 08/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/912,049	REHBERGER ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 07 July 2003.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 3-29 and 41-64 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 3-29 and 41-64 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)

6) Other:

The application should be reviewed for errors. The correct name of the genus recited in claim 3 is "*Propionibacterium*".

The amendment filed 7/7/03 is acknowledged. Claims 3-29 and 41-64 are being considered on the merits.

The disclosure is objected to because of the following informalities: At page 10, the accession numbers of the deposits are missing. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-29 and 41-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-9, 15-16, and 41-64 are vague, indefinite and confusing in that the sole designation of the microorganisms by an internal strain number, which is arbitrary and creates ambiguity in the claims. For example, the microorganisms disclosed in this application could be designated by some other arbitrary means, or the assignment of the strain number could be arbitrarily changed to designate another strain or microorganism. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Amendment of the claim to refer to the deposit accession number of the claimed strain(s) would obviate this rejection.

Claims 10-29 and 46-48 are vague, indefinite and confusing in that there is no claim designated step to ensure that the milk has more protein, more fat and more solids non-fat as well as increases energy balance, plasma leptin level and plasma non-esterified fatty acids levels, since the method encompasses feeding the same microorganism to the same subject in the same amount to obtain substantially different effects. Do different strains have different effects or do all strains have these claim designated effects? How is the desired effect obtained? Clarification is required.

Claims 14 and 15 are vague and indefinite in that it is unclear what is intended by a "microorganism" that "comprises" *P. acidipropionici* or *P. jensenii*. It is recommended that the claim be amended to "wherein the microorganism... is...".

Claims 10-29, 41-44, 46-48, 57-60 and 62-64 are vague and indefinite in the use of words of degree as a limitation such as "increased", "enhanced", "higher percent"; "substantially greater percent".

When a word of degree is used as a limitation, it is necessary to determine whether the specification provides some standard for measuring that degree. See *Seattle Box Company, Inc. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). In this case, the specification does not enable one skilled in the art to reasonably establish what may be construed as being within the metes and bounds of the word of degree. Therefore, one of ordinary skill in the art would not be apprised as to the claimed invention's scope when the claims are read in light of the specification. See *Ex parte Oetiker*, 23 USPQ2d 1641. Here the nature of the ruminants used in the comparison is not revealed and in that the claim designated invention requires that first ruminant be fed a *Propionibacterium* while the second ruminant is feed nothing. Are the animals being starved or are the ruminants fed their normal feed? While it is assumed that the "second ruminant" is to serve as "control", it is noted that to constitute a proper control, the animals should be matched at least with respect to genus/species, gender, age, breed, size and life stage, etc.. It is submitted that a comparison involving a camel and a goat or a bovine such as cows of different breeds with bulls and/or oxen of the same or different breeds is not probative of differences in any parameter whatsoever. Only in claim 23 is it specified that the ruminant appears to be lactating. However, goat milk, sheep milk, camel milk and cow's milk are not equivalent. In addition, there are substantial differences between milk cows such as Holstein, Guernsey, Friesian, Brown Swiss, Ayrshire, Milking Shorthorn and Jersey and also between beef bovines, such as Hereford, Angus, Zebu, Charolais, Brangus, Simmental, Chianina, Dutch Belted, Limousin, for example, in addition to the gender differences mentioned.

In addition, there is no clear indication of the nature and amount of bacteria to be fed to achieve an the results as indicated. It is doubted that feeding a few bacteria is going to have a significant effect.

#### *Response to Arguments*

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

While it is true that applicant can be his/her own lexicographer, there is nothing in the as-filed specification to define each of the strains specifically. It is also noted that strains P160 and P170 cannot be deemed "representative" of strain P179, P195 and P261, since it is apparent

that each of these strains is distinct and is specifically claimed in the process. Claims 3-9 require the strains to be properly defined in order to particularly point out and distinctly claim the subject matter which the applicant regards as his invention.

Applicant argues that claims 10, 23, 41, 46, 58 and 57 require the testing of milk or the ruminant itself after it is feed the microorganism. However, as noted *supra* the claims are devoid of a proper control. In addition, there is no indication in claim 41, for example that the second ruminant is tested.

With respect to the amount of bacteria fed, it is unclear what is fed, since the bacteria "comprise propionibacteria". In addition, the fact that dependent claims indicate the number of bacteria fed, does not confer this limitation to the other claims. Each claim is examined on its own merits.

#### ***Rejections under 35 U.S.C § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

Claims 3-9, 15 and 41-64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The rejection is stated in a previous Office action.

#### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants argue that the enablement requirements are met. However, applicants have failed to fulfill the criteria set forth in 37 CFR 1.801-1.809.

The isolation procedure from rumen as indicated on page 17 of the response fails to provide any assurance that the claimed strains will be isolated. The strains that are claim designated **MUST** be obtainable in a reproducible manner. The claims are not directed to a process of isolation of strains, but rather to specific strains having specific internal designations.

Applicants assert that these strains have the property of being the highest propionate producers of strains having the Group I genotype. There is no assurance of record that these strains can ever be re-isolated. Deposit of all of the strains recited is required. Strains P150 and P170 cannot be deemed "representative" of strain P179, P195 and P261, since it is apparent that each of these strains is distinct given that each strain is specifically claimed in the process.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-29 and 41-64 rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rehberger *et al.* for the reasons as stated in the last Office action and the further reasons below.

Claims 3-29 and 41-64 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ott *et al.* for the reasons as stated in the last Office action and the further reasons below.

#### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Counsel states that the strain of the patents do not have the group I profile produced by an *Xba* I digest of bacterial genomic DNA and were not isolated from cow rumen. The arguments by counsel in this regard have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence.

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In addition, even if the strains are not identical, the claimed process requires the one step of feeding a ruminant a composition comprising a bacterium. Since the amount is not specified, it cannot be readily ascertained whether the touted effects are due to the bacteria or to other components in the composition.

Moreover, the effect of P-63 of reducing acidosis is deemed to have favorable effects at least with respect to the energy balance and weight gain when provided to a ruminant. In addition, Ott *et al.* is directed to weight gain (See, e.g., col. 17, lines 18-26) as well as the production of propionic acid, a volatile fatty acid.. It is noted that an increase in plasma leptin levels is associated with weight gain. In addition all the claim designated invention requires is an unidentified "increase" in certain parameters. The measurement of "energy level" appears uncertain.

Therefore the rejection is deemed proper and it is adhered to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

*Irene Marx*  
IRENE MARX  
PRIMARY EXAMINER